

### III. REMARKS

Claims 1-7 and 15-18 are pending in this application. Claims 1 and 15 are amended. Claims 8-14 were previously canceled. Claims 1-7 and 15-18 are rejected under 35 USC 102(e) as allegedly being anticipated by or in the alternative, under 35 USC 103(a) as allegedly being obvious over (PDR for Herbal Medicines, First Edition, *Salix Species*, pages 1111-1112, copyrighted 1998) (referred to herein as "PDR") or (The Healing Herbs, The Ultimate Guide to the Curative Power of Nature's Medicines, *White Willow*, pages 369-371, copyrighted 1991) (referred to herein as "Healing Herbs"). Applicant respectfully traverses the 35 USC 102(e) and 35 USC 103(a) rejections for the reasons provided below.

Applicant does not acquiesce in the correctness of the rejections and reserves the right to present specific arguments regarding any rejected claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

#### A. REJECTION OF CLAIMS 1-7 and 15-16 UNDER 35 USC §102(e) and 103(a)

With regard to the 35 USC §102(e) and 35 USC §103(a) rejection over PDR or Healing Herbs, Applicant asserts that PDR or Healing Herbs do not teach each and every feature of the claimed invention and PDR or Healing Herbs do not suggest each and every feature of the claimed invention.

Specifically regarding the Office's rejections of claim 1 (and similarly claim 15), Applicant submits that PDR or Healing Herbs fails to teach each and every feature of claim 1 (and similarly claim 15) as amended.

Claim 1 (and similarly claim 15), as amended, recites "said extract contains a first compound with a molecular weight of 263.3 daltons and a second compound with a molecular weight of 356.5 daltons and a third compound with a molecular weight of 337.5 daltons and a fourth compound with a molecular weight of 354.4 daltons." PDR and Healing Herbs do not teach or suggest this feature. The Office does not allege that PDR and Healing Herbs teach or suggest this feature.

In support of these amendments and in further support of Applicant's claimed invention, Applicant submits the declaration of co-inventor George Stefano, Ph.D. Dr. Stefano's declaration specifically identifies four compounds contained with the claimed "pharmaceutical composition." These four "distinct nitric oxide releasing compounds" are "2,3-dihydroxypropyl oleate, bis(m-phenoxyphenyl) ether, 6-acetyl-5,6,6a,7-tetrahydro-4H-dibenzo(de,g)quinoline, and (+)-N-(p-(2-methylbutoxy)benzylidene)-4-(2-methylbutyl)aniline." Dr. Stefano Dec. ¶15.

As described by Dr. Stefano "[the pharmaceutical composition] contains discrete chemical compounds that contribute to additive and/or synergistic evoked stimulation of nitric oxide release. The abilities of these combinations of chemical compounds to evoke the therapeutic release of nitric oxide from constitutive positive physiological sources clearly separate their medicinal properties from those that are categorized within the salicin class of compounds." Dr. Stefano Dec. ¶14.

Healing Herbs describes the water extracts of white willow as an anti-inflammatory. Healing Herbs at p.371. PDR suggests the water extracts of white willow as anti-inflammatory. PDR at p.1112. Both references describe water extracts acting via the salicylate pathway. PDR at p.1112 and Healing Herbs p.370. Thus they act via inhibition of prostaglandin production and by inhibiting nitrous oxide production.

Claim 1 (and similarly claim 15), recite the claimed composition as “stimulating nitric oxide production.” PDR and Healing Herbs do not teach or suggest this feature of the claimed invention.

Applicant asserts that the references cited by the Office fail to identify a composition in any way except as an extract capable of inhibiting nitrous oxide production.

Applicant's declaration has specifically identified four of the compounds contained in the claimed composition. Further, Applicant has shown the compounds' additive and/or synergistic characteristics for “stimulating nitric oxide production.”

The Office asserts that the “stimulating nitric oxide production” as an intended use is not limiting referring to MPEP 2112. Advisory Action 02-02-2009.

Applicant asserts the references cited by the Office provide no intuitive basis to identify the claimed “composition” and the compounds contained within the claimed “composition” because the references teach inhibition of nitrous oxide production.

In the absence of a reference that teaches the features of the claimed invention, Applicant respectfully asserts pursuant to MPEP 2145(X)(A) that the Office has engaged in impermissible hindsight, using Applicant's own teachings in making its

rejection. It is the Applicant's position that, absent its own teachings, the Office's rejection is legally and logically untenable.

Applicant respectfully requests that the Office withdraw the rejection of independent claim 1 (and similarly claim 15), as amended, under 35 USC §102(e) and 35 USC §103(a).

With respect to the dependent claims, Applicant herein incorporates the arguments presented above with respect to the independent claims from which the claims depend. Furthermore, Applicant submits that all dependant claims are allowable based on their own distinct features. Since the cited art does not teach each and every feature of the claimed invention, Applicant respectfully requests withdrawal of this rejection.

#### IV. CONCLUSION

In addition to the above arguments, Applicant submits that each of the pending claims is patentable for one or more additional unique features. To this extent, Applicant does not acquiesce to the Office's interpretation of the claimed subject matter or the references used in rejecting the claimed subject matter. Additionally, Applicant does not acquiesce to the Office's combinations and modifications of the various references or the motives cited for such combinations and modifications. These features and the appropriateness of the Office's combinations and modifications have not been separately addressed herein for brevity. However, Applicant reserves the right to present such arguments in a later response should one be necessary.

In light of the above, Applicant respectfully submits that all claims are in condition for allowance. Should the Examiner require anything further to place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the number listed below.

Respectfully submitted,

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